K122938

SECTION 5. 510(K) SUMMARY

5. 510(K) SUMMARY

510(k) SUMMARY
(per 21 CFR §807.92)

NOV 2 2012

FORUM™

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany +49 3641220-667 (phone) +49 3541220-756 (fax) Establishment Registration Number: 9615030
Contact Person:	Judith A. Brimacombe Director, Clinical/Regulatory Affairs Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 (925) 557-4616 Phone (925) 557-4259 Fax E-mail: j.brimacombe@meditec.zeiss.com
Date prepared:	October 17, 2012
Device	System, Image Management, Ophthalmic
Classification:	21 CFR 892.2050
Device Class:	II
Product Code:	NFJ
Common Name:	Picture Archiving and Communications System
Trade/Proprietary Name:	FORUM™, FORUM Archive, FORUM Archive & Viewer

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PREDICATE DEVICES:

Company:	Carl Zeiss Surgical GmbH
Device:	FORUM (K090439)
Company:	Topcon Medical Systems, Inc.
Device:	Synergy (K093313)

INDICATIONS FOR USE

FORUM is a software system intended for use in storage, management, processing, and display of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications.

FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.

DEVICE DESCRIPTION

FORUM is a computer software system designed for storage, processing, and review of images, videos and reports originating from computerized diagnostic instruments or other documentation systems.

FORUM is available in two different product variants: FORUM Archive and FORUM Archive & Viewer.

The FORUM Archive consists of a server and a client application. The server offers a DICOM interface to diagnostic instruments via a network. On this server, medical documents including reports, images, videos or raw data and patient data are archived. All data can be retrieved via the network by instruments or other applications using the DICOM interface. The client application provides a graphical user interface (GUI) for administering the server and the data stored therein.

FORUM Viewer serves as an additional module to the client application that allows health care professionals to display and review the data stored in FORUM Archive. FORUM Viewer enables health care professionals to perform measurements in fundus images, based on the scaling information which is provided in the DICOM header and add comments to the saved data. FORUM Viewer provides the option for data transfer to and from other FORUM installations and the ability to import non-DICOM data. FORUM Viewer also includes a modality worklist (scheduling).

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FORUM Archive & Viewer provides the following workflow cycle:

- Receive patient demographic data from the leading systems, Electronic Medical Record (EMR) or Hospital Information Systems (HIS) and enter these manually into FORUM
- Transfer patient demographic data from FORUM to diagnostic instruments via modality worklist (scheduling)
- Receive and archive exam data from diagnostic instruments
- Enable health care professionals to display and review exam data through FORUM Viewer

FORUM also interfaces with other FORUM applications such as FORUM ASSIST match. This accessory software provides an improved workflow to identify potential duplicates of patient records that may then be merged using a merge operation already available on FORUM. The relevant supporting documentation for this software is provided within this 510(k).

SUBSTANTIAL EQUIVALENCE

It is the opinion of Carl Zeiss Meditec AG that the new version of FORUM (3.0) is substantially equivalent to the predicate devices FORUM (K090439) and Synergy (K093313). The indications for use statement for FORUM are similar to the indications for use of the predicate devices cited in this application. The technological comparison demonstrates that FORUM is functionally equivalent to the predicate devices.

The similarities and differences between the subject device FORUM and the predicate devices and how these differences do not impact the safety and effectiveness of the device are provided below.

- FORUM and the predicate devices comprise of a central database to store diagnostic documents.
- FORUM and the predicate devices are client-server systems that provide a software application (client) to view the stored data in the database (server).
- FORUM and the predicate devices provide the management, storage and processing and display of patient, diagnostic, video and image data.
- FORUM and the predicate devices can connect to LAN and have DICOM interface.
- FORUM and the predicate device Synergy provide the measurement functionality in imported images whereas the predicate device FORUM (K090439) does not. FORUM provides a line measurement in fundus images, whereas the predicate device Synergy provides line and area measurements of retinal images.

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Additionally, the predicate device Synergy also provides OCT Retinal and RNFL thickness measurement functions. The line measurement function in FORUM has been verified and validated and the results indicate that the difference does not raise new questions of safety and effectiveness.

- FORUM and the predicate device Synergy provide interface with Electronic Medical Records (EMRs) or Practice Management Systems whereas the predicate device FORUM (K090439) does not. This function in FORUM uses the HL7 standard. HL7 is an established protocol, which has been verified with FORUM and the results indicate that the difference does not raise new questions of safety and effectiveness.

- FORUM and the predicate device FORUM (K090439) do not provide access to patient data remotely via the internet. Remote access of data can only be done via the Virtual Private Network (VPN) whereas the predicate device Synergy provides data access remotely via the internet. The difference in this function does not raise new questions of safety and effectiveness.

Evaluation performed on FORUM supports the indications for use statement, demonstrates that the device is substantially equivalent to the predicate devices. The technological characteristics of FORUM are similar to those of the predicate devices. The minor differences between FORUM and the predicate devices are insignificant and do not impact the safety and effectiveness of the device.

TECHNOLOGICAL CHARACTERISTICS

The fundamental technological characteristics of the new version of FORUM (3.0) are similar to those of the predicate devices, FORUM (K090439) and Synergy (K093313). All systems comprise a central database to store diagnostic documents (i.e. retinal images and reports of other ophthalmic diagnostic devices). These documents are imported from the diagnostic devices via a network connection.

All systems are client–server systems which provide a software application (client) to view the data stored in the database (server). FORUM Viewer allows the user to search for patient records and display these for comparison purposes. FORUM interfaces with other FORUM applications, devices and systems. The client software can be used to access the database from a remote location via network.

FORUM and the predicate devices all serve the same principal purpose of clinical usage and provide a wide range of comparable functionality for their users.

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PERFORMANCE DATA

Performance testing was conducted on FORUM and was found to perform as intended. FORUM is DICOM compliant according to its DICOM conformance statement.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on FORUM to ensure that the device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Regulatory Technology Services, LLC
c/o Mark Job
1394 25th Street NW
Buffalo, MN 55313

NOV 2 2012

Re: 510(k) Number: K122938
Trade/Device Name: FORUM Archive, FORUM Archive & Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: October 18, 2012
Received: October 19, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K122938

Device Name: FORUM™

Indications for Use:

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Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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